

(12)

EUROPEAN PATENT APPLICATION

(21) Application number: 89307422.9

(51) Int. Cl. 4: **A61M 5/158**

(22) Date of filing: 20.07.89

(30) Priority: 20.07.88 US 221875

(43) Date of publication of application:
07.02.90 Bulletin 90/06

(64) Designated Contracting States:
DE FR GB

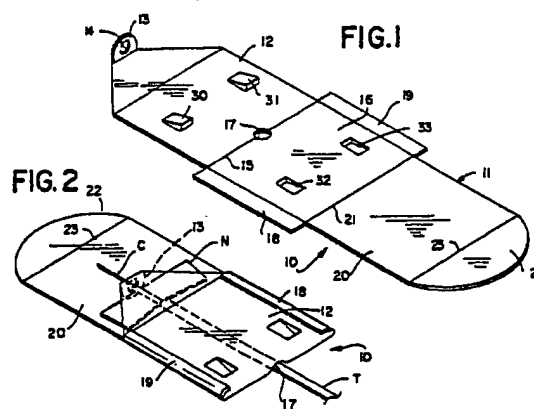
(71) Applicant: **CITY OF HOPE**
1500 East Duarte Road
Duarte California 91010-0269(US)

(72) Inventor: **Hogan, J. Martin**
5737 Avenida Estoril
Long Beach California 90814(US)

(74) Representative: **Sheard, Andrew Gregory et al**
Kilburn & Strobe 30, John Street
London WC1N 2DD(GB)

(54) **A protective sheath for a needle suitable for intravenous use.**

(57) A multi-panel shield or sheath constructed to define an envelope into which an intravenous needle ("N") having a sharpened cannula ("C") may be withdrawn upon removal from a vein. The envelope has a compression flap (20) adapted to overlie the venipuncture site while the needle is being withdrawn from the vein, whereby a nurse, doctor or other person using the device may exert pressure on the venipuncture site as the needle is being withdrawn. A gripping panel (22) is also provided to facilitate holding of the sheath as the needle is being retracted into the envelope. After the needle has been withdrawn into the shield envelope, the panels may be folded over one another to completely enclose the needle for subsequent handling and/or disposal. In some embodiments of the inventions a non-folding sheath defining an envelope is utilized. Other embodiments have no compression panel.



A PROTECTIVE SHEATH FOR A NEEDLE SUITABLE FOR INTRAVENOUS USE

This invention relates to intravenous needles, and more particularly, to protective sheaths therefor.

The danger of disease transmission among personnel who come into contact with contaminated materials or diseased persons, and especially the danger to those exposed to blood or other body fluids, has motivated the development of various devices and methods to prevent inadvertent infection.

It is especially desirable to provide means for protection from accidental pricking or puncture with contaminated intravenous needles. The problem is particularly acute in the collection and handling of blood or other body fluids when needles are used to pierce a vein and/or to transfer such fluids to various receptacles for testing and the like. Such means should be inexpensive, easy to use and provide for easy manipulation of the needle into and out of operative shielded and unshielded relationship.

In response to this problem, various shield devices have been developed to limit the exposure of personnel to the sharp point of the needle. Examples of prior art shields are shown in U.S. patents 4,659,330 and 4,737,114. Each of these patents describes tubular sheaths which encase the needle when the needle is not in use. Other needle protecting devices are disclosed in U.S. patents 2,854,976, 2,990,059, 3,709,223, 3,901,226, 3,973,565, 4,007,740 and 4,170,993. These patents do not suggest a shield envelope into which the needle may be withdrawn as it is removed from the venipuncture site.

It is desirable to provide a shield or protective sheath for an intravenous needle to protect health workers from needle pricks and inadvertent contact with contaminated needles.

Further, it is desirable to provide a sheath that is slidable along associated tubing into covering relationship with a needle during and after retraction from a vein or the like.

The present invention is directed to providing an intravenous needle sheath that includes foldable panels which may be quickly and easily placed into and out of shielding relationship with the needle.

The invention also seeks to provide a needle sheath that includes overlying shielded portions and portions defining gripping means for manipulating the sheath and needle.

It is also desired to provide a needle sheath that includes foldable panels positioned to cover or shield the venipuncture site while the needle is in place and also during and after retraction into the sheath.

According to the present invention there is provided a protective sheath for a needle suitable for intravenous use, the needle having a winged or butterfly-type body and a sharpened cannula, the protective sheath comprising a plurality of panels foldable over one another to define an envelope, including a base plate adapted to lie under a needle and a top panel adapted to overlie the needle, the panels having an opening at a forward end portion thereof for extension therethrough of the sharpened cannula.

Generally, the foldable panels have an opening through a rearward end portion thereof for receiving tubing connected to a needle, the sheath being slidable along the tubing whereby the needle and tubing may be moved axially relative to the sheath to enable the cannula to be extended through the forward opening and to enable the needle to be retracted into the envelope defined by the top panel and base plate with the sharpened point of the cannula positioned within and shielded by the envelope.

Preferably, the top panel and/or the bottom plate have needle retention means thereon for retaining the needle in its retracted position in the envelope.

The protective sheath preferably further comprises a foldable compression panel joined along a fold line to a forward end portion of the top panel, and adapted to be extended over a venipuncture site during withdrawal of the cannula from a vein so that a person using the needle may exert compression on the venipuncture site while being protected from the sharpened point of the cannula.

A gripping tab may be formed on the forward end of the compression panel to enable the sheath to be held in position while the needle is being retracted into the envelope.

An extension flap may project forwardly from the end of the compression panel to extend beyond and shield the venipuncture site when the compression panel is extended to overlie the venipuncture site, thereby shielding the user from the sharpened point of the cannula as it is being withdrawn from a vein.

The gripping tab and extension flap are preferably joined along a common fold line to the forward end of the compression panel.

The extension tab may be jointed to the forward end of the compression panel via a pair of relatively narrow panels connected to each other and to the extension flap and compression panel, respectively, along three parallel, spaced apart fold lines, thereby the two narrow panels may be folded against one another to form the gripping panel.

In the protective sheath it is preferred that a cannula retention tab is formed on the end of the base plate, the retention tab having an opening therethrough for receiving the cannula to maintain the cannula in alignment and in operative relationship with the sheath.

A cannula retention tab may be formed on the end of the base plate, the retention tab having an opening therethrough for receiving the cannula to maintain the cannula in alignment and in operative relationship with the sheath, the cannula retention tab also extending the base plate sufficiently forward to allow the cannula wings to be folded upward without interference from the top panel.

The cannula retention tab is preferably formed on the end of the base plate, the retention tab having an opening therethrough for receiving the cannula to maintain the cannula in alignment and in operative relationship with the sheath.

In the protective sheath the retention means preferably comprises a raised projection or ramp on opposite sides of the base plate configured to enable the wings of the needle to ride rearwardly thereover but prevent reverse, forward movement of the wings over the projections.

The opposite side edges of the top panel and base plate may be secured to one another.

The sheath may be made of molded synthetic plastics material.

Alternatively, the sheath may be made of paper composition.

Some embodiments of the present invention provide a protective sheath for an intravenous needle having a sharpened cannula and a winged butterfly type body attached to a length of tubing the sheath comprising an envelope including a base panel adapted to lie under a needle and a top panel adapted to overlie the needle, the envelope having an opening at a forward and rearward portion thereof through which the tubing may be passed, the opening at the forward position of the envelope being adapted for extension of the cannula therethrough, the sheath being slidable along the tubing, whereby the needle and tubing may be moved axially relative to the sheath to enable the cannula to be extended through the forward opening for insertion of the cannula into a vein, and to enable the needle to be retracted into the envelope defined by the top panel with the sharpened point of the cannula positioned within and shielded by the envelope.

In some embodiments of the invention there is provided a novel multipanel shield or sheath which is folded to define an envelope into which the needle may be withdrawn after use, and which has a flap adapted to overlie the venipuncture site while the needle is being withdrawn from a vein. This flap may also serve as a compression plate

through which a nurse, doctor or other person using the device may exert pressure on the venipuncture site as the needle is being withdrawn. A gripping panel is also provided to facilitate holding of the sheath as the needle is being retracted into the envelope. After the needle has been withdrawn into the shield envelope, the panels may be folded over one another to completely enclose the needle for subsequent handling and/or disposal.

Other embodiments of the invention provide needle sheaths with a non-folding compression panel and with no compression panel.

A better understanding of the present invention will become apparent from the following detailed description and accompanying drawings, given by way of example only, wherein like reference characters designate like parts throughout the several views, and wherein:

Figure 1 is a top perspective view of the blank used to make a first form of sheath in accordance with the invention, showing the sheath in unfolded conditions.

Figure 2 is a bottom perspective view of the sheath of Figure 1, showing the sheath folded to define an envelope and with an intravenous needle in place for insertion into the vein of a patient and with the compression flap and gripping panel extended over the needle.

Figure 3 is a top perspective view of the sheath of Figure 2.

Figure 4 is a top plan view of the sheath and needle combination of Figures 2 and 3, showing the sheath and needle in position for insertion into the vein of a patient.

Figure 5 is a side view in elevation of the sheath and needle combination of Figure 4.

Figure 6 is a front view of the sheath and needle combination of Figure 5.

Figure 7 is a side view similar to Figure 5, but with the wings on the needle or cannula set in an erect position.

Figure 8 is a similar view to Figure 6 with the wings folded up.

Figure 9 is a top plan view of the sheath and needle combination of Figures 2-8, showing the needle inserted into the vein of a patient.

Figure 10 is a top plan view of the sheath and needle combination of Figures 2-8, showing the needle retracted into the shield envelope.

Figure 11 is a top plan view of the first modification, in which a flap extension is provided beyond the point of attachment of the gripping panel.

Figure 12 is a side view of the sheath of Figure 11.

Figure 13 is a schematic side view of the sheath of Figures 11 and 12, showing the manner of use of the sheath.

Figure 14 is a top plan view of the sheath and needle combination of Figures 11-13, showing the needle inserted into a vein and the flap extension projecting beyond the venipuncture site.

Figure 15 is a view similar to Figure 14, but showing the needle retracted into the shield envelope,

Figure 16 is a plan view of the blank used in forming a second modification of the invention in which the gripping panel is defined by a pair of folded panels between the compression plate and the flap extension.

Figure 17 is a side view of the second modification of the invention.

Figure 18 is a side view of the sheath of Figure 17, shown in partially folded condition and with a needle enclosed in the shield envelope.

Figure 19 is a top plan view of a third modification of the invention, in which the sheath is identical to that shown and described in relation to Figures 1-9, except that the cannula retention tab has been eliminated.

Figure 20 is a top plan view of the sheath of Figure 19, showing the sheath moved into position adjacent the needle.

Figure 21 is a top plan view of a fourth modification of the invention, in which guide tabs are formed on the bottom plate.

Figure 22 is a top plan view of the sheath of Figure 21, showing a needle in operative position in the sheath.

Figure 23 is a side view of a further modification of the invention in which the compression panel and upper plate are a single non-folded element.

Figure 24 is a top plan view of the embodiment of the invention shown in Figure 23.

Figure 25 is a rear perspective view of the invention shown in Figure 23.

Figures 26, 27 and 28 illustrated the manner of use of the device shown in Figures 23-25.

Figure 29 is a sectional view of another modification of the invention which does not include a compression plate.

Figure 30 is a top plan view of the device as shown in Figure 29.

Referring more specifically to the drawings, a first form of shield or sheath in accordance with the invention is indicated generally at 10 in Figures 1-10. In Figure 1, the unfolded blank 11 for the sheath of the invention shown in perspective view and comprises a base plate 12 over which a winged or butterfly needle "N" lies when in use. A cannula retention tab 13 is formed on the free end of the base plate 12 and has an opening 14 therethrough for receiving the sharpened cannula "C" of needle "N". The other end of the base plate is joined at a fold line 15 with a top plate 16 which is

adapted to overlie the needle when in use. An opening 17 is formed through the shield at the fold line for receiving the tubing "T" leading to Needle "N". A pair of side tabs 18 and 19 extend along the sides of top plate 16 and are folded and secured over the adjacent edges of the base plate when the top plate and base plate are folded into overlying relationship with one another about fold line 15, as shown best in Figure 2. These side tabs maintain the top plate and base plate in folded relationship and define an envelope for receiving the needle (see Figures 2, 4 and 10).

A compression plate 20 is joined to the other end of the top plate 16 along fold line 21, and a gripping plate or tab 22 is joined at fold line 23 to the opposite end of the compression plate. Thus, when the panels are folded into operative relationship, the compression plate and gripping plate or tab project beyond the end of the needle as shown in Figures 2 and 3. Consequently, the sharpened end of the cannula is shielded to protect the user from accidental pricking or contact therewith. Further, after the needle has been inserted into a patient's vein, the compression plate may overlie the venipuncture site (see Figure 3).

Additionally, the base plate has a pair of needle retention or locking ramps 30 and 31 formed therein, upstanding from the plane of the base plate. A pair of mating recesses 32 and 33 are formed in the top plate in position to receive the locking ramps when the base plate and top plate are folded over one another. Thus, when the cannula is withdrawn from the vein of the patient and the needle is retracted into the envelope, the wings of the needle ride over the ramps and engage behind them, retaining or locking the needle into shielded position within the envelope (see Figure 10).

For inserting the cannula into the vein of a patient, the compression plate 20 and gripping tab 22 are folded about their respective fold lines to position the compression plate above the top plate, as shown in Figures 4-10, and the wings of the needle are bent upwardly to enable them to be gripped for insertion of the cannula into the vein. Tape, with or without a gauze pad, may then be placed over the venipuncture site and over at least portions of the wings of the needle to retain the cannula in place. The compression plate and gripping tab may be left in their folded positions shown in Figures 4-10 until it is desired to remove the cannula from the vein. Then, the compression plate is extended over the venipuncture site so that the nurse, doctor or other person removing the cannula may apply pressure to the venipuncture site while the cannula is withdrawn from the vein by pulling the tubing back to retract the needle into the envelope. During this time, the gripping tab is

grasped to retain the shield in position and to enable the needle to be retracted into the envelope and past the locking ramps. Accordingly, protection to the user from the sharpened point of the cannula is assured at all times. Moreover, the compression plate acts as a shield to prevent blood from spurt-
ing onto the user as the cannula is being with-
drawn.

A first modification to the invention is indicated generally at 40 in Figures 11-15. In this form of the invention, an extension panel 41 is joined to the end of compression plate 20 at fold line 23, whereby the gripping tab 22 is positioned such that even further protection is afforded to the user as the cannula is being withdrawn from the vein (see Figure 13). During insertion of the cannula into the vein, the extension panel and gripping tab are folded under as shown in Figures 11 and 12. However, for withdrawal of the cannula from the vein, the compression plate 20, extension plate or panel 41 and gripping tab 22 are extended forwardly over the venipuncture site as shown in Figures 14 and 15. The extension panel, by extending beyond the venipuncture site, provides added protection to the user. Otherwise, use of this form of the invention is identical to that previously described.

A second modification to the invention is indicated generally at 50 in Figures 16-18. In this form of the invention, which is similar to that described immediately above, the gripping tab 22 is replaced with a further pair of fold lines 51 and 52 on opposite sides of the fold line 21 joining the compression plate 20 to the extension panel 41. Thus, by further folding the panels about the fold lines 51 and 52, a gripping tab 53 is formed at the juncture between the extension panel and the compression panel. This arrangement eliminates any difficulties which may be encountered in forming or attaching the earlier described gripping panel 22. In addition, as shown by dot-and-dash lines in Figure 16, the cannula retention tab 13 and its function may be eliminated, if desired. This enables the shield to be moved along the length of tubing connected to the needle so that the shield may be moved out of the way when not needed, thereby providing room for use of a second needle. For example, a first needle aligned toward the wrist of a patient may be inserted into a vein, while a second needle aligned toward the elbow maybe inserted into a vein. In some instances when two needles are used as just described, use of a shield with the cannula retention tab results in interference between the two needles and their associated shields or sheaths.

A third modification to the invention is indicated generally at 60 in Figures 19 and 20. This form of the invention is identical to the first form of the invention described herein, except that the cannula

retention tab 13 and its function are eliminated, resulting in the advantage described immediately above. Consequently, the needle may be positioned with the cannula inserted into a vein and secured as shown in Figure 19, with the sheath slid along the tubing to an out-of-the-way position. When it is desired to remove the cannula from the vein, the sheath is slid along the tubing into contiguous relationship with the needle as shown in Figure 20 and used as described before.

A fourth modification to the invention is indicated generally at 70 in Figures 21 and 22. In this form of the invention, the sheath 71 includes three panels, i.e., a base plate 72, top plate 73 and a compression panel 74 joined along a fold line 75 to the forward edge of the top plate. A pair of up-standing needle retention tabs 76 and 77 in the base plate and cooperating recesses 78 and 79 in the top plate retain the needle in the sheath after it is retracted into the shield envelope as previously described. The top plate and base plate may be formed as a single sheet joined along a fold line 80 at the rearward ends thereof, as in the previously described forms of the invention, and subsequently sealed to one another along adjacent side edges 81 and 82 to form the envelope. The base plate is formed with forwardly projecting guide tabs 83 and 84, defining a notch or recessed area 85 which is aligned with the needle to facilitate guiding of the needle during its insertion into a vein. The compression panel maybe extended to overlie the venipuncture site during withdrawal of the cannula, as shown in Figure 21, or folded back over the top plate during insertion and use of the needle, as shown in Figure 22.

The sheath may be made from any suitable material, such as molded synthetic plastic, metal, paper composition, etc. If made from molded plastic or paper materials, the side tabs 18 and 19 may be sealed to the top plate with an adhesive or heat seal of other suitable means, as desired or appropriate. Alternatively matching side tabs may be added to the top plate and sealed to the opposing side tabs without folding.

Figures 23-28 depict a fifth embodiment of the invention 70 in which the compression panel and upper plate are a single non-folded element 85. In this embodiment the compression panel is permanently extended. The element 85 may be provided with gripping surfaces or panels 86 and 87.

The manner of use of the device is apparent from Figures 26-28. Referring to the Figures, the device is initially spaced on the tube away from the needle "N". The device is then moved upwards along the tube to encase the needle in the envelope. The tube is then grasped and pulled rearwardly to move the needle "N" past the locking ridges upon removal from the vein or the like.

A sixth embodiment of the invention is shown in Figures 29 and 30. As there depicted, the invention comprises a pair of front and back convex shaped panels 87 and 88 which may be made of plastic material. The convex portion of the device provides resistance for the movement of the needle backwards and forwards within the device. The manner of use is similar to that described with respect to the embodiment shown in Figures 23-28. This embodiment may also be provided with locking ridges in which case the panels may be essentially parallel.

Although the invention has been described with reference to a particular embodiment, it is to be understood that this embodiment is merely illustrative of the application of the principles of the invention. Numerous modifications may be made therein and other arrangements may be devised without departing from the spirit and scope of the invention.

Claims

1. A protective sheath for a needle suitable for intravenous use, the needle having a winged or butterfly-type body and a sharpened cannula, the protective sheath comprising:

a plurality of panels foldable over one another to define an envelope, including a base plate adapted to lie under a needle and a top panel adapted to overlie the needle, the panels having an opening at a forward end portion thereof for extension therethrough of the sharpened cannula.

2. A protective sheath as claimed in Claim 1, characterised in that the foldable panels have an opening through a rearward end portion thereof for receiving tubing connected to the needle, the sheath being slidable along the tubing whereby the needle and tubing may be moved axially relative to the sheath to enable the cannula to be extended through the forward opening and to enable the needle to be retracted into the envelope defined by the top panel and base plate with the sharpened point of the cannula positioned within and shielded by the envelope.

3. A protective sheath as claimed in Claim 1 or 2, characterised in that the top panel and/or the bottom plate have needle retention means thereon for retaining the needle in its retracted position in the envelope.

4. A protective sheath as claimed in any one of the preceding claims, characterised in that it further comprises a foldable compression panel joined along a fold line to a forward end portion of the top panel, and adapted to be extended over a venipuncture site during withdrawal of the cannula from a vein so that a person using the needle may exert

compression on the venipuncture site while being protected from the sharpened point of the cannula.

5. A protective sheath as claimed in Claim 4, characterised in that a gripping tab is formed on the forward end of the compression panel to enable the sheath to be held in position while the needle is being retracted into the envelope.

6. A protective sheath as claimed in Claim 5, characterised in that an extension flap projects forwardly from the end of the compression panel to extend beyond and shield the venipuncture site when the compression panel is extended to overlie the venipuncture site, thereby shielding the user from the sharpened point of the cannula as it is being withdrawn from a vein.

7. A protective sheath as claimed in Claim 6, characterised in that the gripping tab and extension flap are joined along a common fold line to the forward end of the compression panel.

8. A protective sheath as claimed in Claim 6, characterised in that the extension flap is joined to the forward end of the compression panel via a pair of relatively narrow panels connected to each other and to the extension flap and compression panel, respectively, along three parallel, spaced apart fold lines, whereby the two narrow panels may be folded against one another to form the gripping panel.

9. A protective sheath as claimed in any one of the preceding claims, characterised in that a cannula retention tab is formed on the end of the base plate, the retention tab having an opening therethrough for receiving the cannula to maintain the cannula in alignment and in operative relationship with the sheath.

10. A protective sheath as claimed in any one of the preceding claims, characterised in that a cannula retention tab is formed on the end of the base plate, the retention tab having an opening therethrough for receiving the cannula to maintain the cannula in alignment and in operative relationship with the sheath, the cannula retention tab also extending the base plate sufficiently forward to allow the cannula wings to be folded upward without interference from the top panel.

21.08.99

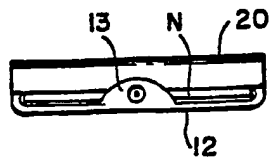


FIG. 6

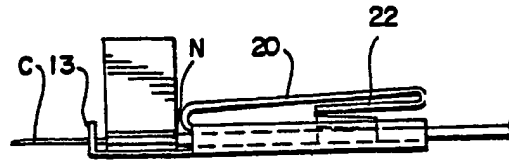


FIG. 7

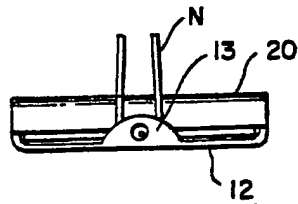


FIG. 8

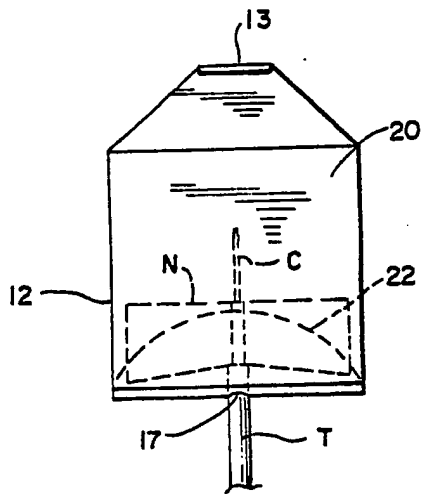


FIG. 10

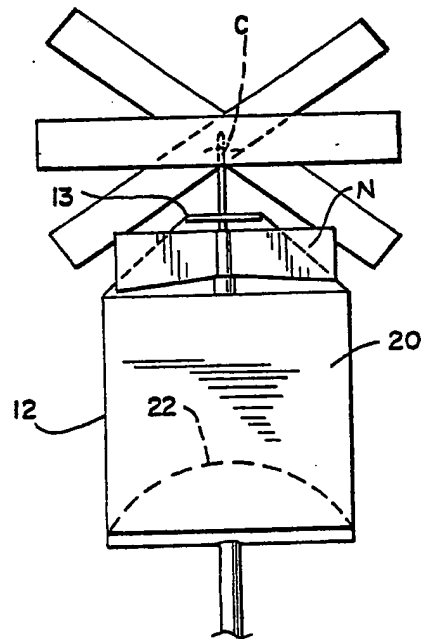


FIG. 9

FIG. 11

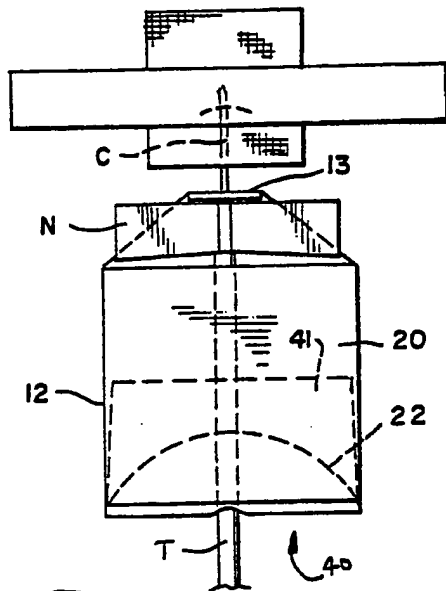


FIG. 12

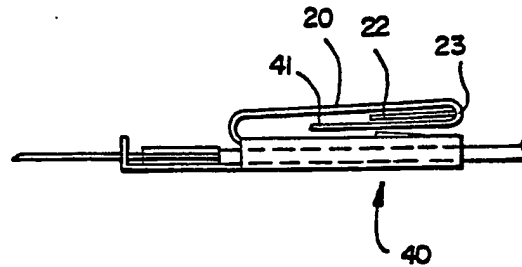


FIG. 13

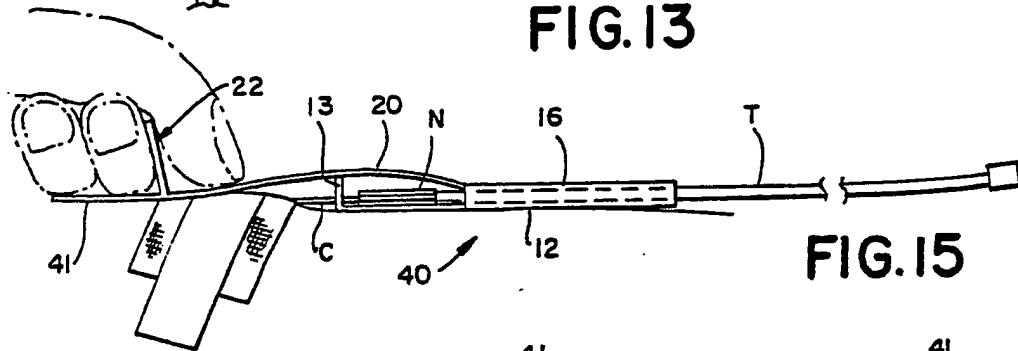
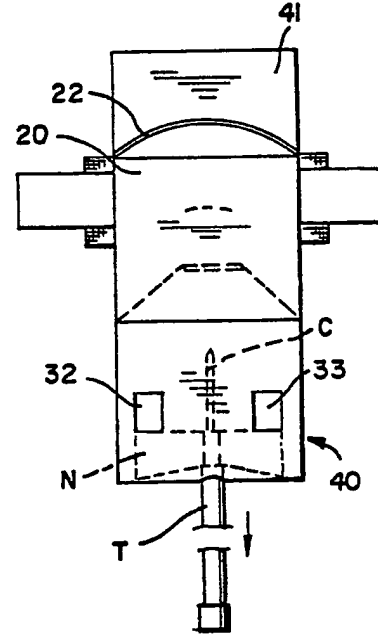
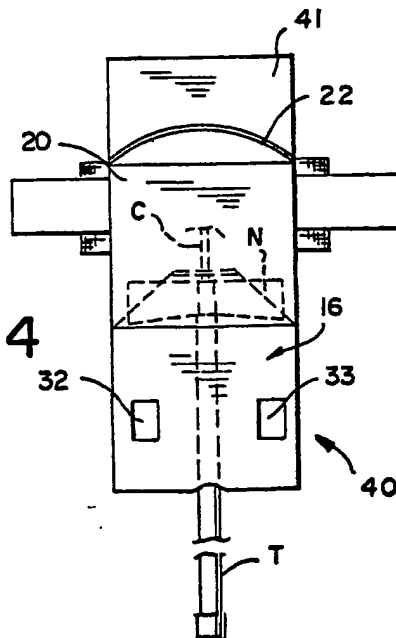


FIG. 15

FIG. 14



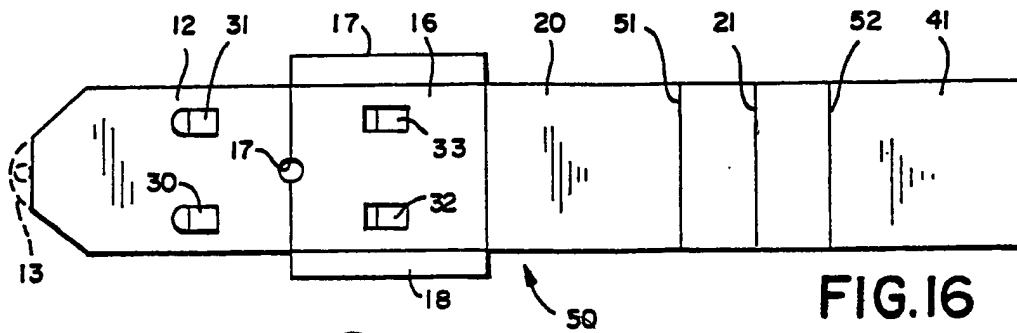


FIG. 16

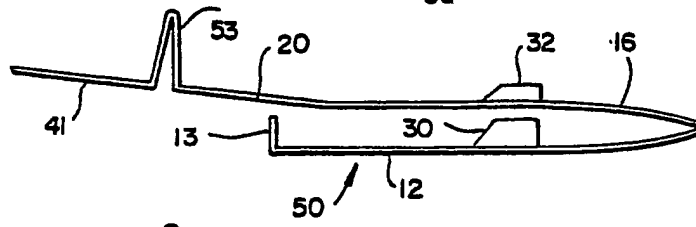


FIG. 17

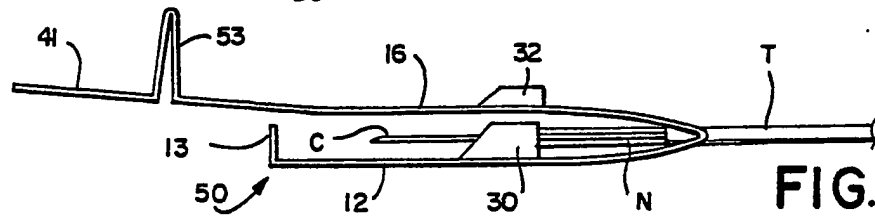


FIG. 18

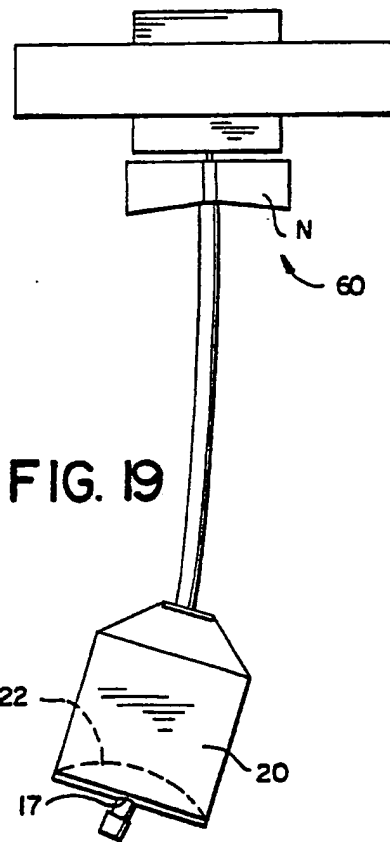


FIG. 19

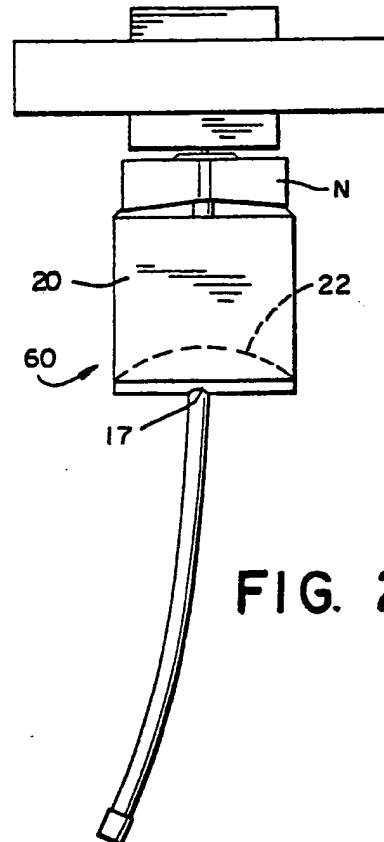


FIG. 20

FIG. 21

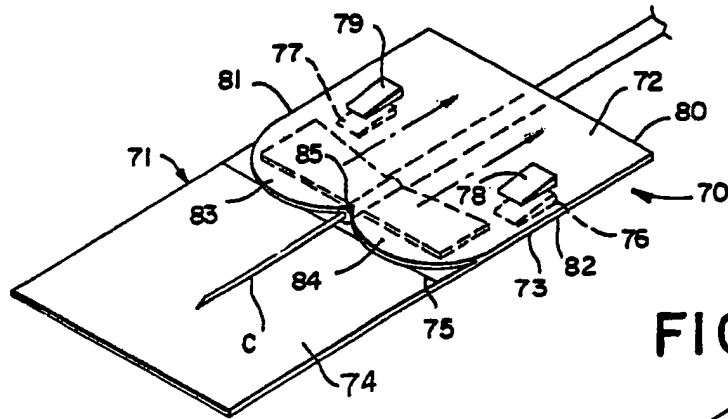


FIG. 22

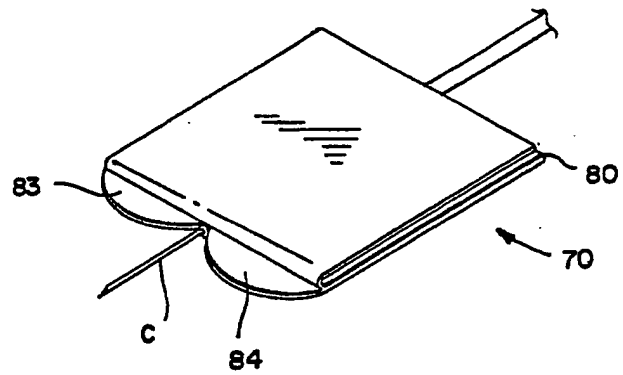


FIG. 23

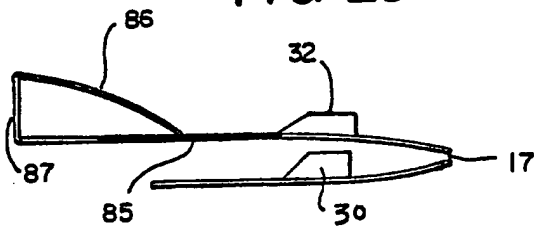


FIG. 24

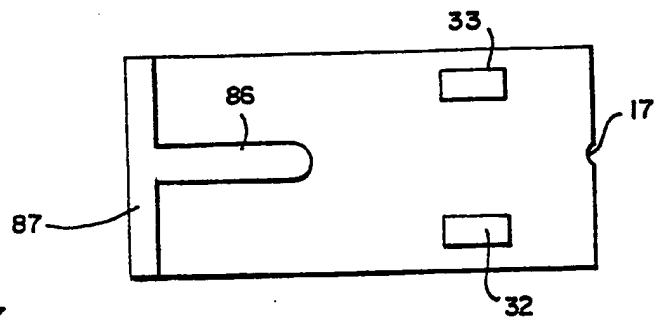
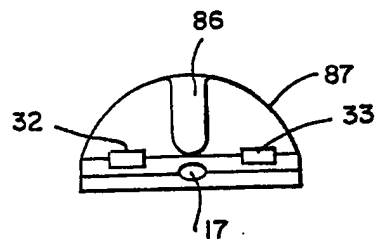


FIG. 25



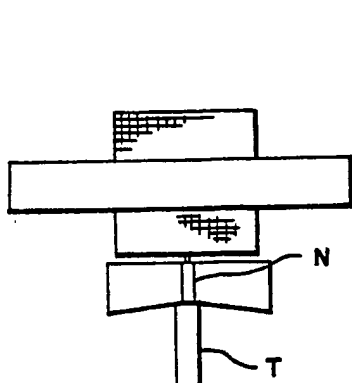


FIG. 26

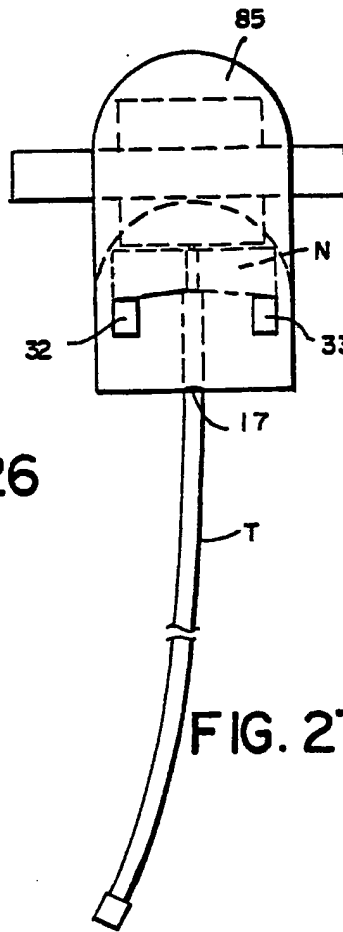
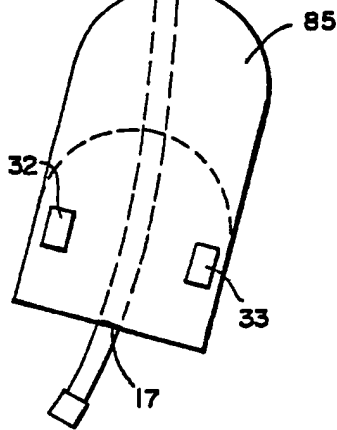


FIG. 27

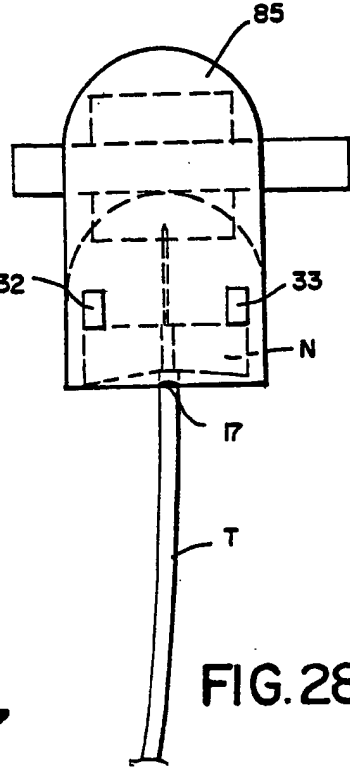


FIG. 28

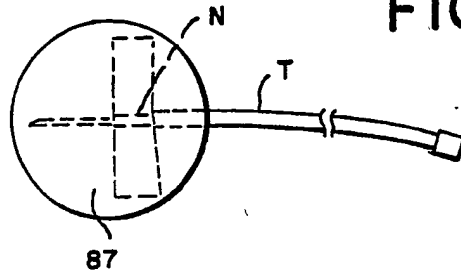
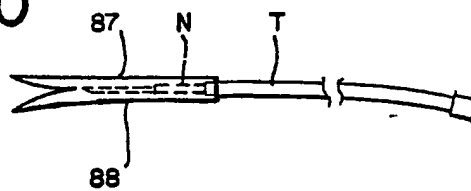


FIG. 29

FIG. 30





European Patent
Office

EUROPEAN SEARCH REPORT

Application Number

EP 89 30 7422

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
X	EP-A-0 265 159 (CITY OF HOPE MEDICAL CENTER) * Figures 3-6; column 2, line 38 - column 3, line 13; column 4, line 46 - column 5, line 18; column 5, line 4 *	1-3	A 61 M 5/158
A	---	5	
A,D	US-A-3 973 565 (STEER) * Figures 7,8,10; column 1, lines 52-67; column 2, lines 32-45; column 6, lines 58-64; column 7, lines 10-39 * -----	1,2,4,5 ,9	
			TECHNICAL FIELDS SEARCHED (Int. Cl.5)
			A 61 M
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 06-11-1989	Examiner SEDY, R.
<div>CATEGORY OF CITED DOCUMENTS</div> <div>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</div> <div>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons ----- & : member of the same patent family, corresponding document</div>			